GUIDELINE C-4
(formerly 14-05)

The Management of Biomedical Waste in Ontario

Legislative Authority:

Environmental Protection Act, RSO 1990, Part V, Sections 19 and 27; Part XVII, Section 197

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Director, Program Development

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Table of Contents

1.0 INTRODUCTION

2.0 DEFINITIONS

3.0 MANAGEMENT OF BIOMEDICAL WASTE ON-SITE

3.1 Segregation and Packaging
3.2 Storage of Biomedical Waste

4.0 TRANSPORTATION OF BIOMEDICAL WASTE OFF-SITE

4.1 General Requirements
4.2 Where the Generator Transports Less than 5 Kilograms
4.3 Where the Generator Transports More than 5 Kilograms
4.4 Vehicle Standards

5.0 TREATMENT AND DISPOSAL OF BIOMEDICAL WASTE

5.1 Incineration
5.2 Non-incineration
5.3 Discharge to Sanitary Sewer

6.0 BIOMEDICAL WASTE TREATMENT FACILITIES

6.1 On Site Treatment
6.2 Off-site Treatment

7.0 FINAL DISPOSAL OF TREATED BIOMEDICAL WASTE

7.1 Packaging for Final Disposal
7.2 Transportation for Final Disposal
7.3 Landfilling of Treated Biomedical Waste

APPENDIX 1

SCHEDULE 5A - Agents of Biomedical Animal Wastes
SCHEDULE 5B - Agents of "Other" Biomedical Wastes Requiring Special Handling

APPENDIX 2 - Universal Biohazard Symbol

SYNOPSIS

The primary purpose of this guideline is to clearly define biomedical waste and to specify handling and management requirements for this waste stream. The guideline is intended to ensure the proper and safe management of biomedical waste, prior to the promulgation of the necessary amendments to O. Regulation 347, and to provide direction to generators, carriers and receivers of biomedical waste, Ministry staff and the public when issues related to the management of biomedical waste arise.

The guideline will be enforced by including appropriate conditions on Certificates of Approval for carriers and receivers.

1.0 Introduction

Biomedical waste results from the provision of human or animal health care, related medical research and teaching, the operation of laboratories, morgues and funeral establishments, the use of biotechnology (such as the production and testing of vaccines), and from mobile health care activities.

Although these wastes represent less than ten percent of the wastes generated in health care, biomedical wastes present a hazard to public health and safety and, therefore, must be segregated and managed accordingly.

This guideline defines biomedical waste and provides guidance for the management of this waste stream, including criteria for handling, packaging, transportation, treatment and disposal.

2.0 Definitions

Biomedical Waste:

Waste that is generated by:

(A) human health care and residential facilities,

(B) animal health care facilities,

(C) medical research and medical teaching establishments,

(D) veterinary research and veterinary teaching establishments,

(E) health care teaching establishments for human health care,

(F) health care teaching establishments for animal health care,

(G) clinical testing or research laboratories,

(H) the professional office of a health professional within the meaning of the *Regulated Health Professions Act, 1991*,

(I) the professional office of a member of the College of Veterinarians of Ontario,

(J) mortuaries and funeral establishments, including any similar establishments for pets and other animals,

(K) facilities involved in the production and testing of vaccines,

(L) facilities involved in mobile health care for humans,

(M) facilities involved in mobile health care for animals.

Biomedical waste is limited to:

(a) human anatomical waste, consisting of tissues, organs and body parts, not including teeth, hair and nails;

(b) animal waste, consisting of all tissues, organs and body parts, carcasses, bedding, liquid blood or semi-liquid blood and blood products, items contaminated with blood that would release liquid or semi-liquid blood or blood products if compressed, body fluids visibly contaminated with blood and body fluids removed in the course of surgery, treatment or necropsy, unless determined by the generator, and so certified in writing by the generator, that the waste does not contain any of the agents listed in Schedule 5A (see Appendix 1);

(c) non-anatomical waste, limited to:

(c) (i) human and animal cultures, stocks or specimens, excluding urine and faeces submitted for analysis, live or attenuated vaccines, cell lines, and material that has come into contact with any of the items in this sub-clause;

(c) (ii) human liquid blood or semi-liquid blood and blood products, items contaminated with blood or blood products that would release liquid or semi-liquid

blood if compressed, body fluids visibly contaminated with blood, and body fluids removed in the course of surgery, treatment, autopsy, embalming or for diagnosis, excluding urine and faeces;

(c) (iii) sharps including needles, needles attached to syringes, and blades; or

(c) (iv) broken glass or other materials which are capable of causing punctures or cuts and which have come into contact with human blood or body fluid or in contact with animal blood or animal body fluid unless determined by the generator, and so certified in writing by him or her, that the waste does not contain any of the agents listed in Schedule 5A (see Appendix 1);

(d) other waste which:

(d) (i) is determined by the generator to require careful handling such as other biomedical waste received;

(d) (ii) has come into contact with a human or animal being treated for or suspected to be infected with one or more of the agents listed in Schedule 5B (see Appendix 1);

or

(d) (iii) is cytotoxic waste;

but does not include waste that is:

- from animal husbandry;
- domestic waste;
- controlled in accordance with the *Health of Animals Act* (Canada), the *Dead Animal Disposal Act* (Ontario), the *Meat Inspection Act* (Ontario), or the *Meat Inspection Act* (Canada); or
- generated in food production, general building maintenance or office administration at one of the facilities mentioned in clauses (A) to (M).

Cytotoxic Drugs:

Drugs possessing a specific destructive action designed specifically to destroy certain cells, including antineoplastic drugs that selectively kill dividing cells;

Cytotoxic Waste:

Waste cytotoxic drugs and includes: (a) leftover or unused cytotoxic drugs, and (b) tubing, tissues, needles, gloves and any other things which have come into contact with a cytotoxic drug;

Existing Hospital Incinerator:

An incinerator put into operation before the 31st day of December, 1985 and owned by a hospital within the meaning of the *Public Hospitals Act* at which biomedical waste, but no hauled liquid industrial waste or other hazardous waste, is incinerated;

Health Care Facilities:

Human health care and residential facilities and animal health care facilities;

"animal health care facilities" means veterinary hospitals and veterinary clinics;

"human health care and residential facilities" means the following facilities intended for the care of human beings:

(a) A hospital as defined in the *Public Hospitals Act* or in the *Community Psychiatric Hospitals Act*.

(b) A laboratory or specimen collection centre as defined in the *Laboratory and Specimen Collection Centre Licensing Act*.

(c) A private hospital as defined in the *Private Hospitals Act*.

(d) A psychiatric facility as defined in the *Mental Health Act*.

(e) A nursing home as defined in the *Nursing Homes Act*.

(f) A home as defined in the *Homes for the Aged and Rest Homes Act*.

(g) An approved charitable institution as defined in the *Charitable Institutions Act* that is approved, under that Act, as one of the following classes:

(g)(i) halfway houses where rehabilitative residential group care may be provided for adult persons;

(g)(ii) homes where residential group care may be provided for handicapped or convalescent adult persons, and an approved charitable home for the aged.

(h) A facility designated by the regulations under the *Developmental Services Act* as a facility to which that Act applies.

(i) A facility where any of the following are provided: child development services or child treatment services, as defined in the *Child and Family Services Act*, or child and family intervention services, as defined in O. Regulation 70 (RRO 1990).

(j) A home for retarded persons as defined in the *Homes for Retarded Persons Act* other than an auxiliary home as defined in O. Regulation 635 (RRO 1990) where persons live in a supported independent living setting.

(k) A cancer centre established by the Ontario Cancer Treatment and Research Foundation under the *Cancer Act.*

(l) Independent health facilities within the meaning of the *Independent Health Facilities Act.*

Mobile Health Care:

Human or animal health care provided at a location which is not,

(a) a health care facility,

(b) the professional office of a health professional within the meaning of the *Regulated Health Professions Act, 1991*,

(c) the professional office of a member of the College of Veterinarians of Ontario.

Modified Biomedical Waste Incinerator:

An incinerator which is to undergo major modification to the incinerator and/or its air pollution control system, process or mode of operation.

New Biomedical Waste Incinerator:

An incinerator which was approved on or after January 23, 1989.

Sharps:

Medical or veterinary implements and equipment intended to be

sharp for the purpose of cutting or piercing;

Treated Biomedical Waste:

Biomedical waste which has been treated utilizing the following treatment criteria:

(a) where the biomedical waste is comprised of the items described in (c)(i) of the definition of biomedical waste, treatment by autoclaving to the point of producing at least a 99.9999% reduction in spores of *bacillus stearothermophilus*;

(b) where the biomedical waste is not,

a biomedical waste mentioned in clause (a), or human anatomical waste, animal waste, cytotoxic waste, or waste which has come into contact with a human or animal being treated for or suspected to be infected with one or more of the agents listed in Schedule 5B (see Appendix 1)

either,

(i) treatment by autoclaving to the point of producing at least a 99.99% reduction in spores of *bacillus stearothermophilus*, or

(ii) chemical treatment or thermal treatment, other than incineration or autoclaving, to the point of producing at least a 99.99% reduction in spores of *bacillus stearothermophilus* or *bacillus subtilis.*

3.0 Management of Biomedical Waste On-Site:

3.1 Segregation and Packaging

Generators shall undertake the necessary steps to ensure that biomedical waste is not placed in containers with other hospital wastes.

To minimize both the physical and biological hazard associated with waste sharps (needles, scalpels, blades, etc.), sharps shall be placed into a puncture-resistant leak-proof container dedicated specifically for that purpose. The sharps container shall have a lid which can not be removed once it has been permanently closed.

Generators of sharps shall be strongly discouraged from including disinfecting solutions or chemicals in sharps containers; the use of chemicals or disinfectants does not eliminate the biological

and physical hazards associated with sharps, and additional treatment is still required.

The sharps container must be marked with the universal biohazard symbol displayed in Section 8 and labelled "Biomedical Waste/Déchets Biomédicaux".

Other biomedical waste shall be segregated into either a plastic bag or rigid container with a non-removable lid and labelled "Biomedical Waste/Déchets Biomédicaux". The container shall be capable of withstanding the weight of the biomedical waste without tearing, cracking or breaking.

All biomedical waste containers shall be colour-coded:

(a) red -- where the biomedical waste is being transported to an incineration facility; or

(b) yellow -- where the biomedical waste is being transported to a non-incineration facility.

3.2 Storage of Biomedical Waste

Human anatomical and animal anatomical waste stored by the generator shall be stored at a temperature at or below 4 degrees Celsius. Sharps and broken glass do not require refrigerated storage. Other non-anatomical wastes stored for greater than four days after generation shall also be stored as specified above.

Biomedical waste storage areas at a generator's site may include a permanent area specifically designed and constructed for the refrigerated storage of biomedical waste, or a stand-alone refrigeration/freezer unit. Biomedical waste storage areas are commonly located at or near the receiving area of the generator's site, which in many cases is in the vicinity of food supply and preparation areas. It is essential that biomedical waste storage areas are kept locked, except where authorized personnel are on hand.

The facility shall be clearly marked as being a biomedical waste storage area with a sign that is no smaller than 20 cm by 20 cm and which states "biomedical waste storage area" and "site d'entroposage des déchets biomédicaux" and has the universal biohazard symbol (see Section 8.0) clearly displayed.

Biomedical waste storage areas shall be physically separate from food preparation or supply areas of the facility. No materials other than biomedical waste shall be stored in the facility.

4.0 Transportation of Biomedical Waste Off-Site

4.1 General Requirements

Where the primary biomedical waste container is a sharps container or a rigid container with a non-removable lid, additional packaging or containment of the biomedical waste is not necessary for off-site transportation. The container shall be labelled and colour-coded in accordance with Section 3.0, above.

Where the primary container is a plastic bag, the bag shall be placed into a rigid outer-container for transportation off-site. The outer container may be a box, rigid container or reusable rigid container and should be leak-proof. The outer container must be labelled and colour-coded as specified in Section 3.0.

Prior to transportation off the generator's site biomedical waste containers shall be sealed, locked or closed such that no biomedical waste is likely to be released or discharged during transportation.

Reusable outer containers shall be cleaned with a disinfecting solution prior to reuse.

4.2 Where the Generator Transports Less than 5 Kilograms.

Where biomedical waste is to be transported off-site for treatment or disposal by the generator and the weight of the biomedical waste is less than 5 kilograms in total, the generator is exempt from the requirements of Sections 18 and 19 of O. Regulation 347 and Section 27 of the *Environmental Protection Act (EP Act)* as long as the biomedical waste is labelled and packaged in accordance with Sections 3.0 and 4.0 of this guideline, and,

(a) the biomedical waste is accompanied by a health care professional or worker in the health care industry or related industry who is trained for that purpose; and

(b) the generator maintains written records of the date, quantity and destination of the biomedical waste transported for a minimum of two years.

The generator may transport such biomedical waste to a facility licensed appropriately under the *EP Act* or to a biomedical waste generation facility which is willing to accept transported biomedical waste and deal with it appropriately.

4.3 Where the Generator Transports More than 5 Kilograms

When biomedical waste is to be transported off-site for treatment

or disposal by the generator and the biomedical waste is 5 kilograms or more, Sections 18 and 19 of Regulation 347 and Section 27 of the *EP Act* apply. The generator shall obtain a Provisional Certificate of Approval for a waste management system issued under Part V of the *EP Act.*

The generator shall package the biomedical waste as stipulated in this guideline; all shipments shall require manifesting, and the biomedical waste shall only be transported to an existing hospital incinerator or a facility for which a Certificate of Approval has been issued which authorizes the acceptance of biomedical waste.

Where the generator is transporting biomedical waste to a hospital incinerator on the day in which the biomedical waste is scheduled for incineration, or the receiving facility has sufficient refrigerated storage capacity, the standards for biomedical waste transportation vehicles described below may be waived in the Certificate of Approval.

4.4 Vehicle Standards

The following biomedical waste transportation vehicle standards apply to: the generator which transports greater than 5 kilograms; all parties acting on behalf of a generator; and any third party biomedical transportation service where any or all types of biomedical waste are transported.

When only sharps are transported, these requirements may be waived in the Certificate of Approval permitting transportation.

All transportation vehicles shall be specially designed to accommodate the special interest to be served by the vehicle. The following features shall be provided in the storage compartment:

(a) The storage compartment shall be insulated and must be kept refrigerated at a temperature at or below 4 degrees Celsius.

(b) Walls and floor shall be metal surfaced to ensure effective cleaning and disinfecting.

(c) The floor shall be sealed and leak-proof. A liquid retaining lip shall be provided above the floor level at the door opening.

(d) No windows or ventilating openings shall open into the storage compartment.

(e) Only one lockable door shall provide access into the storage compartment.

(f) An interior light shall be provided.

(g) The universal biohazard symbol (see Section 8.0) shall be prominently displayed on the outside of the left and right vertical surfaces of the storage compartment.

(h) The vehicle shall not be used for any other purpose than transporting biomedical waste.

(i) The storage compartment door shall be kept locked at all times during transportation or when the vehicle is parked, except for normal entry.

(j) At the end of each day of operation, the interior compartment of the vehicle shall be thoroughly cleaned with a disinfecting solution.

5.0 Treatment and Disposal of Biomedical Waste

5.1 Incineration

In addition, incineration technologies shall be used to treat anatomical waste of human or animal origin which has come into contact with an individual being treated for or suspected to be infected with one or more of the agents listed in Schedule 5B of this Guideline: "Agents of "Other" Biomedical Wastes Requiring Special Handling", and for cytotoxic waste. These technologies must meet the requirements of Guideline A-1: "Combustion and Air Pollution Control Requirements for New Municipal and Biomedical Waste Incinerators".

5.2 Non-incineration

Non-incineration technologies may be used to treat other biomedical wastes. The technologies, other than autoclaves shall be capable of inactivating spores of *B. stearothermophilus* or *B. subtilis* by 99.99%. If the technology is an autoclave, it shall be capable of inactivating spores of *B. stearothermophilus* by 99.99%. The Ministry may establish other treatment criteria from time to time.

5.3 Discharge to Sanitary Sewer

A waste generator may discharge blood, blood products or body fluids from the waste generation facility into a sewage works subject to the Ontario Water Resources Act, or into a sewage works established before the 3rd day of April, 1957, or into a sewage system, as defined by Part VIII of the *EP Act*.

6.0 Biomedical Waste Treatment Facilities

6.1 On-Site Treatment

Where a biomedical waste treatment facility is located on a generator's site and meets the standards specified in Section 5.2 above, the facility is exempt from Sections 27, 40 and 41 of the *EP Act*. For each day the facility is in operation, it must keep a written record of the date, volume and final disposition of biomedical waste treated, including any biomedical waste accepted from generators operating under the exemptions described in Section 4.2 of this guideline. Such written records shall be kept by the treatment facility for a minimum of two years.

6.2 Off-site Treatment

Where a biomedical waste treatment facility is not located at the generator's site, and accepts off-site biomedical waste for treatment, Sections 27, 40 and 41 of the *EP Act* apply.

7.0 Final Disposal of Treated Biomedical Waste

7.1 Packaging for Final Disposal

Treated biomedical waste generated by the facility shall be stored separately from biomedical waste and other municipal waste.

Prior to leaving the site for final disposal, treated biomedical waste shall be packaged in a bag capable of withstanding the weight of the waste without tearing, cracking or breaking, or in a container that is rigid and puncture-resistant. Where the treated biomedical waste contains sharps which have not been shredded, a bag can not be used. The container shall be rigid and puncture-resistant. The package shall be clearly labelled "Treated Biomedical Waste" including the words "Not Hazardous" and "Certified". The operator of the site shall sign, near the word "Certified", to certify that the waste in the container or package has been subjected to appropriate treatment to render the contents of the bag or container treated biomedical waste.

7.2 Transportation for Final Disposal

Treated biomedical waste shall be transported, as directly as may be practicable, to the final disposal site. No other waste shall be transported in the vehicle with treated biomedical waste. Treated biomedical waste shall not be transported to a transfer station or other facility where final disposal will not take place.

The waste storage compartment of the vehicle shall be enclosed and must not be a compaction-type waste haulage vehicle. The vehicle shall have on hand, at all times, suitable emergency spill clean-up equipment.

Any treated biomedical waste which becomes loose or is in a container that is punctured, broken or leaking shall be immediately re-packaged in a suitable bag.

7.3 Landfilling of Treated Biomedical Waste

Treated biomedical waste shall be deposited at the landfill site only under the supervision of the operator of the site or a person designated by the operator. Persons operating site machinery or the transport truck are not considered supervisors for the purposes of this Section.

Once the treated biomedical waste is deposited in the site, a minimum of 125 centimetres of other waste or cover material shall be deposited over the treated biomedical waste. This ensures that direct contact between site equipment and treated biomedical waste is avoided.

APPENDIX 1

SCHEDULE 5A - AGENTS OF BIOMEDICAL ANIMAL WASTES

SCHEDULE 5B - AGENTS OF "OTHER" BIOMEDICAL WASTES REQUIRING SPECIAL HANDLING

Schedule 5A
Agents of Biomedical Animal Wastes

Bacteria

- Bacillus anthracis
- Brucella - all species
- Francisella tularensis, type A (biovar tularensis)
- M. tuberculosis
- Pseudomonas malleri; P. pseudomallei
- Yersinia pestis

Viruses

- Arenaviridae
  - Lymphocytic choriomeningitis virus, neurotropic strains
- Bunyaviridae
  - Unclassified Bunyavirus
    - Hantaan, Korean haemorrhagic fever and epidemic nephrosis viruses
- Herpesviridae
  - Gammaherpesvirinae
    - Genus Rhadinovirus: Herpesvirus ateles; Herpesvirus saimiri
- Retroviridae
  - Oncovirinae
    - Genus Oncornavirus C
      - Human T-cell leukaemia/lymphoma virus (HTLV-I, HTLV-II,if cultured)
    - Genus Oncornavirus D
      - Mason-Pfizer monkey virus
      - Viruses from primates
  - Lentivirinae
    - Human immunodeficiency viruses (HIV - all isolates if cultured)
- Rhabdoviridae
  - Genus Vesiculovirus
    - Piry
  - Genus Lyssavirus
    - Rabies, street virus
- Togaviridae
  - Genus Alphavirus
    - Eastern equine encephalitis virus
    - Chikungunya (recent isolates)
    - Venezuelan equine encephalitis (except Strain TC-83)

Unclassified Viruses
    Chronic infectious neuropathic agents (CHINAs)
        Kuru, Creutzfeldt-Jakob agent (also listed under Level 2; level of the suspected agent depends on the nature of the manipulations and the amount of sera, bio/necropsy materials handled)

Arenaviridae
    Lassa, Junin, Machupo viruses

Bunyaviridae
    Genus Nairovirus
        Crimean-Congo haemorrhagic fever

Filoviridae
    Marburg virus
    Ebola virus

Flaviviridae
    Tick-borne encephalitis complex, including -
        Russian Spring-Summer Encephalitis
        Kyasanur forest virus
        Omsk haemorrhagic fever virus

Herpesviridae
    Alphaherpesvirinae
        Genus Simplexvirus: Herpes B virus (Monkey B virus)

Poxviridae
    Genus Orthopoxvirinae
        Variola
        Monkeypox

Parasites

Echinococcus (gravid segments)

Schedule 5B

Agents of "Other" Biomedical Wastes Requiring Special Handling

Bacteria

- Rickettsi
  - Coxiella burnetii

Viruses

- Arenaviridae
  - Lassa, Junin, Machupo viruses
- Bunyaviridae
  - Genus Nairovirus
    - Crimean-Congo haemorrhagic fever
- Filoviridae
  - Marburg virus
  - Ebola virus
- Flaviviridae
  - Tick-borne encephalitis complex, including -
    - Russian Spring-Summer Encephalitis
    - Kyasanur forest virus
    - Omsk haemorrhagic fever virus
- Herpesviridae
  - Alphaherpesvirinae
    - Genus Simplexvirus: Herpes B virus (Monkey B virus)
- Poxviridae
  - Genus Orthopoxvirinae
    - Variola
    - Monkeypox

APPENDIX 2

UNIVERSAL BIOHAZARD SYMBOL

Universal Biohazard Symbol

The actual symbol shall be no smaller than 10 cm by 10 cm and no larger than 40 cm by 40 cm. Unless otherwise specified, the width of the symbol should be approximately one quarter the width of the surface on which it appears. The symbol and its background must be in contrasting colours.